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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/774,478 | 02/10/2004 | Michael Kreindel | KREINDEL4A | 8926 |

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EXAMINER

PEFFLEY, MICHAEL F

ART UNIT

PAPER NUMBER

3739

DATE MAILED: 03/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/774,478

Applicant(s)

KREINDEL, MICHAEL

Examiner

Michael Peffley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 2/10/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 6-8 and 12-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Shadduck ('909).

Shadduck discloses a system for treating sub-surface tissue to shrink collagen fibers. The device includes an electrode array (40) and a light fiber (30) for delivering both forms of energy to tissue. The examiner maintains that the laser from the light fiber (i.e. temperature effector) would inherently heat tissue to create a temperature difference between target and skin tissue. In particular, the spot size, energy and pulse durations (see col. 9, lines 15-22) would yield the same energy intensity as set forth in claim 7. The examiner maintains that providing the same energy intensity level for the same pulse period would inherently provide the same temperature gradient in tissue. The method of using the device is inherent to the structure/disclosure and is fully supported in the Shadduck disclosure.

Claims 1, 4-6 and 9-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Knowlton (5,755,753)

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Knowlton provides a system analogous to the Shadduck system in that it is used for shrinking collagenous tissue. The device includes one or more electrodes (26) located on a temperature effector (18) which cools surrounding tissue through circulating fluid. Knowlton specifically teaches that the thermal gradient creates at least a 30-80 degrees C difference between the target tissue and the skin tissue (see col. 3, line 25-30 and col. 7, lines 12-25). Knowlton also teaches the specific microprocessor and control mechanism to control the delivery of the cooling fluid and RF energy.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 6-8 and 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Taylor (5,509,916) in view of the teachings of Shadduck (6,053,909).

Taylor discloses a device which combines the use of RF and laser energy to treat tissue. In particular, Taylor provides two electrodes (16,20) configured to be attached to the skin, and also delivers laser energy (i.e. temperature effector) to the tissue through the device. The laser energy may be fired first, and the examiner maintains that the laser energy inherently will increase the temperature of the tissue. The use of the pre-heating with thermal energy enhances the delivery of RF energy to tissue. Taylor fails to specifically disclose a temperature gradient of at least 5°C. The method of operating the device is inherent to the structure and is fully supported in the Taylor disclosure.

With regard to the specific temperature gradient of the tissue, the Shadduck system discloses an analogous device for treating tissue using optical energy to heat tissue prior to treating tissue with RF energy. In particular, Shadduck discloses energy intensity levels and time durations (see column 9) that are within the ranges disclosed in the instant application. As such, the examiner maintains that the Shadduck disclosure teaches of providing the same temperature gradient in tissue since providing the same energy and intensity to tissue would inherently yield the same result in tissue.

Thus, to have provided the Taylor system with a pre-heating laser fluence to cause the claimed temperature gradient in tissue to enhance treatment with RF energy would have been an obvious consideration for one of ordinary skill in the art in view of the teaching of Shadduck.

Claims 1, 4-6 and 9-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stern (6,413,255) in view of the teaching of Knowlton (5,755,753).

Stern provides an apparatus for treating tissue which includes one or more RF electrodes (16) for heating a target region, and a temperature effector comprising a cooling means (48,52) which creates a temperature difference between the target tissue and surrounding tissue such that the target tissue is at a higher temperature (see columns 11 and 12). Stern fails to disclose the specific temperature gradient that is created by the pre-cooling mechanism.

As asserted above, Knowlton discloses an analogous device and specifically teaches that the thermal gradient created includes a 30-80 degrees C difference

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between the target tissue and the skin tissue (see col. 3, line 25-30 and col. 7, lines 12-25). Knowlton also teaches the specific microprocessor and control mechanism to control the delivery of the cooling fluid and RF energy, as does the Stern device.

To have provided the Stern device with the claimed temperature gradient in tissue to enhance treatment with RF energy would have been an obvious consideration for one of ordinary skill in the art in view of the teaching of Knowlton.

Conclusion

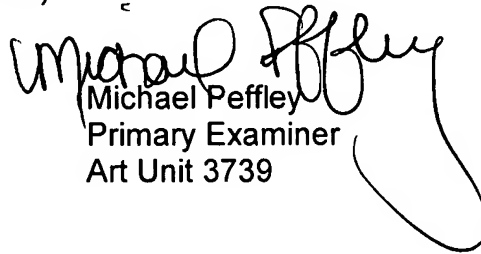
The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Ingle et al (6,139,569) discloses another system that utilizes surface cooling to treat deeper tissue regions with RF energy.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Peffley whose telephone number is (571) 272-4770. The examiner can normally be reached on Mon-Fri from 6am-3pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Michael Peffley
Primary Examiner
Art Unit 3739

mp
March 13, 2006